NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ABBOTT LABORATORIES and FOURNIER LABORATORIES IRELAND, LTD.., Plaintiff, v. IMPAX LABORATORIES, INC. *et al* Defendants.	**Hon. Dennis M. Cavanaugh** **OPINION** (Markman Hearing) Consolidated Civil Action No. 10-cv-1322

DENNIS M. CAVANAUGH, U.S.D.J.:

This matter comes before the Court by request of Abbott Laboratories and Fournier Ireland Ltd. ("Plaintiffs") and Impax Laboratories, Inc. *et al* ("Defendants") for a claim construction hearing, pursuant to Local Patent Rule 4.5. The parties sought the Court's interpretation of disputed terms in U.S. Patent No. 7, 259, 186 ("the '186 patent"). A Markman hearing was held on May 24, 2011 at which both parties ably presented sophisticated and intelligent arguments. Having considered the parties' written and oral arguments, the Court has set forth its construction of the disputed terms.

I. BACKGROUND

A Markman hearing was held to aid the Court in construction of disputed terms in U.S. Patent No. 7, 259, 186 ("the '186 patent"). The '186 patent concerns salts of the drug fenofibric acid, as well as pharmaceutical formulations thereof. This patent is used by Plaintiff to produce and market a prescription drug product, Trilipix, which is used for treating cholesterol and triglyceride

problems in adults. Defendants each filed Abbreviated New Drug Application forms ("ANDA") with the U.S. Food and Drug Administration seeking to market generic versions of Trilipix. Plaintiff contends that the products described in the ANDA's would infringe the '186 patent, which is not set to expire until 2025.

II. LEGAL STANDARD

Claim construction is a matter of law to be determined solely by the court. Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005), cert. denied, 546 U.S. 1170 (2006). Analysis of a patent infringement claim is a two-step process. Tate Access Floors, Inc. v. Interface Architectural Resources, Inc., 279 F.3d 1357, 1365 (Fed. Cir. 2002). A court must first construe the meaning and scope of the patent claims, Markman v. Westview Instruments, Inc., 52 F.3d 967, 978 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996), and then compare the claims as construed to the alleged infringing product. Tate, 279 F.3d at 1365. At this stage, the Court will only engage in the first step.

To construe the terms of a patent, a court should look first to the language of the claim itself. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). Terms within a claim "are generally given their ordinary and customary meaning." Id. "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Phillips, 415 F.3d at 1313.

To determine how a person of skill in the art would understand a patent's claim language, a court must first examine the intrinsic record–the patent itself, including the claims, the specification and the prosecution history. Vitronics, 90 F.3d at 1582 (citing Markman, 52 F.3d at

979). The specification "acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." Id. Indeed, the Federal Circuit has explained that the specification is "usually . . . dispositive . . .[and is the] best guide to the meaning of a disputed term." Phillips, 415 F.3d at 1315 (quoting Vitronics, 90 F.3d at 1582)(internal quotations omitted). It is proper for a court to "rely heavily on the written description for guidance as to the meaning of the claims." Id. at 1317.

A patent's prosecution history is also a critical source of guidance, as it "provides evidence of how the PTO and the inventor understood the patent." Id. The prosecution history is the complete record of the proceedings before the PTO, and "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." Id. The Federal Circuit has repeatedly emphasized the need to consult the prosecution history to "exclude any interpretation that was disclaimed during prosecution." See Rhodia Chimie v. PPG Indus., 402 F.3d 1371, 1384 (Fed. Cir. 2005) (recognizing that, in exchanges with the PTO, a patent applicant may disavow or disclaim certain claim coverage, thereby precluding any claim interpretation that would encompass the disavowed or disclaimed subject matter).

After consulting intrinsic evidence, a district court may also examine extrinsic evidence—i.e., "all evidence external to the patent and prosecution history." Markman, 52 F.3d at 980; Phillips, 415 F.3d at 1317-18 (stating that the Federal Circuit "ha[s] authorized district courts to rely on extrinsic evidence"). Such evidence consists of testimony by the inventor or by experts, dictionaries, and treatises. Markman, 52 F.3d at 980. However, extrinsic evidence is generally "less significant than the intrinsic record in determining the legally operative meaning of claim language." C.R. Bard, Inc.

v. U.S. Surgical Corp., 388 F.3d 858, 862 (Fed. Cir. 2004) (quotations omitted). Extrinsic evidence, when relied upon, must be considered in view of the specification and prosecution history. Phillips, 415 F.3d at 1320. ("[E]xtrinsic evidence may be useful to the court, but it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of intrinsic evidence.").

III. DISCUSSION

A. CLAIM 8

Claim 8 of the '186 Patent contains four disputed terms. Claim 8 reads:

"A pharmaceutical formulation in a form of a molecular dispersion comprising:

i. a salt of fenofibric acid selected from the group consisting of choline, ethanoalamine, diethanolamine, piperazine, calcium and tromethamine; and

ii. a binder component comprising at least one enteric binder."

1. Molecular Dispersion

The parties differ as to the construction of the phrase "molecular dispersion" in claim 8. To begin with the Court notes the instruction of the Federal Circuit in *Catalina Marketing International, Inc. v. Coolsavings.com, Inc*. 289 F.3d 801, 808 (C.A.Fed. (Ill.),2002) that "whether to treat a preamble as a limitation is a determination 'resolved only on review of the entire[ ] ... patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim.'" *Corning Glass Works v. Sumitomo Electric U.S.A., Inc.,* 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed.Cir.1989); *see also Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.,* 98 F.3d 1563, 1572-73, 40 USPQ2d 1481, 1488 (Fed.Cir.1996).

Defendant contends that the use of "a pharmaceutical formulation in a form of molecular dispersion" in the preamble to claim 8 constitutes a structural limitation. The Court agrees. Plaintiff

maintains that eliminating the disputed term, "molecular dispersion," from the preamble would still have created a complete invention, and as such the disputed term is essentially superfluous and therefore can not, as a matter of law, be a structural limitation despite the Patent's pervasive and consistent references to the invention being "in a form of molecular dispersion." Plaintiff refers the Court to *Catalina Marketing International, Inc. v. Coolsavings.com, Inc*. 289 F.3d 801, 808 (C.A.Fed. (Ill.),2002), and to the conclusion that "deletion of the disputed phrase from the preamble of Claim 1 does not affect the structural definition or operation of the terminal itself. The claim body defines a structurally complete invention." The *Catalina* Court, however, was construing a very different term, one that the Court concluded described an intended use. Such is not the case here. Defendant argues convincingly that the prosecution history of the '186 patent indicates that as originally written, claim 8 did not contain the disputed phrase at all. It seems clear that Plaintiff felt the need to refine the claim that appeared in the provisional application to contain the "molecular dispersion" language. This strongly suggests to the Court that Plaintiffs believed this phrase was "necessary to give life, meaning, and vitality" to the claim. *Pitney Bowes, Inc. v. Hewlett-Packard Co.* 182 F.3d 1298, 1305 (C.A.Fed. (Conn.),1999).The choice to include the phrase in the preamble to claim 8 had to have been something more than capricious or merely permissive and referring to one of many embodiments, as Plaintiff's argument seems to suggest. Plaintiff argues that the claim can survive the deletion of the disputed phrase in tact as a complete invention, but that fails to explain why it was added in the first place. Words have meaning, particularly when they are as carefully chosen as they need to be for a patent. The words "molecular dispersion" clearly limit the form and scope of the claimed invention. To suggest that they are there for no other purpose than to describe a preferred embodiment, not a structural limitation on what had been invented in the first

place, makes no sense. While it is true that the phrase was not added to distinguish prior art, that does not lead to the conclusion that it is not a structural limitation. Plaintiff is correct that "if the body of the claim 'sets out the complete invention,' the preamble is not ordinarily treated as limiting the scope of the claim." *Bicon, Inc. v. Straumann Co.* 441 F.3d 945, 952 (C.A.Fed. (Mass.),2006) citing *Schumer v. Lab. Computer Sys., Inc.,* 308 F.3d 1304, 1310 (Fed.Cir.2002). The Court goes on to say, however, that "the preamble is regarded as limiting if it recites essential structure that is important to the invention or necessary to give meaning to the claim." *NTP, Inc. v. Research In Motion, Ltd.,* 418 F.3d 1282, 1305-06 (Fed.Cir.2005), *cert. denied,* 546 U.S. 1157, 126 S.Ct. 1174, 163 L.Ed.2d 1141 (2006); *SanDisk Corp. v. Memorex Prods., Inc.,* 415 F.3d 1278, 1284 n. 2 (Fed.Cir.2005), *cert. denied,* 546 U.S. 1076, 126 S.Ct. 829, 163 L.Ed.2d 707 (2005). A reader skilled in the art reading claim 8 without the disputed phrase would have no idea what the invention actually was; they would only know the ingredients, but not the form. To use a baking analogy, there are many recipes that contain flour, butter and sugar, but without a guide that tells the baker that he is making cookies or a cake, the actual form of the product, the baker would not know what the recipe claimed to be for. A recipe that doesn't say "butter, flour and sugar in the form of a cookie" would be incomplete. A mere "pharmaceutical formulation" would not have created a complete invention. The placement of this phrase in the preamble, and, as Defendant points out, the fact that claims 14 and 15 are dependent on it, and that the phrase is used in conjunction with the term "the present invention" both belie Plaintiff's argument that the phrase is just permissive. The phrase "molecular dispersion" is clearly intrinsic, structural and necessary to an understanding of the patent's scope.

Having concluded that "molecular dispersion" is, in fact, a structural limitation, the Court

now turns to the proper construction of the phrase "molecular dispersion." Plaintiff's proposed construction is "a pharmaceutical formulation in which at least part of the active pharmaceutical ingredient in the formulation is homogeneously dispersed in the binder component." Defendant's proposed construction is "a system in which the individual molecules of the salt of fenofibric acid are homogeneously dispersed in the binder component, and the dispersed substance is free of interfaces."

As defined in the body of the patent, "the term 'molecular dispersion' as used herein and as known to one skilled in the art, describes systems in which a substance, in the present case at least part and particularly the predominant part of the fenofibric acid content, is homogeneously dispersed in the binder component. In a molecular dispersion, the dispersed substance is free of interfaces" (9:5-15).

Defendant's references to the intrinsic evidence of the patent do not support their proposed construction, and the extrinsic evidence that they provide from a medical encyclopedia that defines "dispersion" does nothing to further their construction. Plaintiff's construction more closely follows the plain language, but should be slightly modified. The Court will accordingly derive its construction of the term from a composite of the parties' proposed definitions. *See, e.g., CA, Inc. v. Simple.com, Inc.*, 2009 U.S. Dist. LEXIS 25241, at *103 (E.D.N.Y. Mar. 5, 2009); *Taltech Ltd. v. Esquel Enters.,* 410 F. Supp. 2d 977, 997 (W.D. Wash. 2006). Thus, the Court's construction of a "pharmaceutical formulation in a form of a molecular dispersion" is "a system in which at least part of the active pharmaceutical ingredient in the formulation is homogeneously dispersed in the binder component, and is free of interfaces."

2. Binder Component

Plaintiff proposes to give this term its "ordinary meaning," which they define as "a pharmaceutically acceptable binder." Defendant proposes "a matrix forming excipient in which the individual molecules of the salt of fenofibric acid are embedded and homogeneously dispersed, thereby forming a solid solution of the active substance in the binder."

Defendant's citations to the intrinsic evidence are unavailing. Plaintiff has the better of the argument, since in the body of the patent language, the term "binder component" is used as a generic term, and clearly has an ordinary meaning to one skilled in the art. Thus, Plaintiff's are correct in relying on the ordinary meaning. Defendant raises a novel issue, and directs the Court to *O2 Micro Intern. Ltd. v. Beyond Innovation Technology Co., Ltd.* 521 F.3d 1351, 1361 (C.A.Fed. (Tex.),2008) for the proposition that "a determination that a claim term 'needs no construction' or has the 'plain and ordinary meaning' may be inadequate when a term has more than one 'ordinary' meaning or when reliance on a term's 'ordinary' meaning does not resolve the parties' dispute." As the Court previously noted, terms within a claim "are generally given their ordinary and customary meaning." *Vitronics Corp. v. Conceptronic, Inc.,* 90 F.3d 1576, 1582 (Fed. Cir. 1996). The problem with Defendant's reasoning is that it contemplates no logical end to the Court's role in claim construction. The parsing of words could go on *ad absurdum,* and Courts would forever have to construe ordinary words and even punctuation marks. Not only would the process be infinite, but in the end it would create more confusion than clarity. Words must be held to mean what they say they mean in the context

they are placed. The Court can not torture more out of "binder component" than its customary meaning.

3. Enteric Binder

Plaintiff proposes the following construction, taken verbatim from the patent, that an enteric binder may be defined as "a binder whose solubility or swellability increases with increasing pH and decreases with decreasing pH."(5:54-56). Defendant's proposed construction is "a binder, the solubility or swellability of which increases with increasing pH and vice versa, and excluding the nonenteric binders identified at column 7, line 59-column 8, line 33." The intrinsic evidence cited by Defendant does not support their construction. 7:56-59 reads "if at least one other (non-enteric) binder is present, it is preferred that said other (non-enteric) binder be selected from the group consisting of:," which is then followed by a long list of non-enteric binders that Defendant proposes to include in their construction. The Court fails to understand how a list of non-enteric binders helps to construe the meaning of the disputed phrase, which is "enteric binder." Also, the conditional language ("if...it is preferred") does not support their construction. Plaintiff's construction is preferred.

4. Enteric

Plaintiff contends that "no construction is needed as 'enteric' is only used in the claims within the phrases 'enteric polymer' and 'enteric binder,' which are already being construed. Plaintiff argues that if construction is necessary, it should be consistent with the use of enteric in the agreed upon construction of 'enteric polymer'– namely, enteric is an adjective that describes something that is 'preferentially soluble in the less acid environment of the

intestine relative to the more acid environment of the stomach." Defendant's proposed construction is to define enteric as "resistant to solution in acidic gastric fluid but disintegrable in the more alkaline environment of the intestine." This construction is at odds with the patent language, as cited by both parties, at 6:35-37. Although the patent says that "the binder component can be designed to remain intact in the acidic environment of the stomach (preventing recrystallization of the active substance in the stomach), but dissolve in the more alkaline environment of the intestine," Defendant's proposed construction does not fully track that language. As extrinsic evidence, Defendant cites to a book entitled "Pharmaceutical Sciences" that does not define enteric, except in the context of "enteric coated tablets." That is too far removed to be useful. If Defendant wishes to have the Court construe "enteric" independently from the Court's construction of "enteric binder," it is disingenuous to do so by citing "enteric coated tablet" as the source of the preferred construction. The Court declines to construe "enteric binder."

IV. CONCLUSION

The Court, in accordance with the discussion above, has construed the terms of the '186 Patent.

S/ Dennis M. Cavanaugh
DENNIS M. CAVANAUGH, U.S.D..J.

Date: July 25, 2011
Original: Clerk's Office
cc: All Counsel of Record
The Honorable Joseph A. Dickson, U.S.M.J.